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10/771,845	02/04/2004	Andrew G.C. Frazier	MVMDINC.019A	9741

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EXAMINER	
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ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/771,845

Applicant(s)

FRAZIER ET AL.

Examiner

Melissa Ryckman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/8/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-13, 15, 16 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-13, 15, 16, and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/8/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to arguments and claims filed 6/8/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 7, 9, 10, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Peavey et al. (US 2003/0225421).

Regarding Claim 1, Peavey teaches a method of closing a patent foramen ovale having a septum primum (14) and a septum secundum (16), comprising: providing a closure device having a proximal end (26), a distal end (40), a proximal segment (22), an intermediate segment (36, 38) and a distal segment (44), the proximal and intermediate segments defining a first clip-shaped portion and the intermediate and distal segments defining a second clip-shaped portion (figs. 3a and 11), wherein the closure device is self-expandable (para. 55, made of shape memory material) to a deployment shape wherein the proximal, intermediate and distal segments are generally

parallel (figs. 3a and 11) to one another; deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in a channel between the septum primum and the septum secundum (fig. 3b); and locking the position of the closure device after deployment (fig. 3b, the device is locked because of the friction provided between the septums and the device, according to the applicants specifications, paragraph 112, the lock can be a friction fit) wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (par. 42).

Regarding Claim 2, Peavey teaches the method of claim 1, wherein the intermediate (38) and distal (44) segments of the closure device when deployed are positioned along surfaces of the septum primum (14) and the proximal (22) and intermediate segments (38) of the closure device when deployed are positioned along surfaces of the septum secundum (16, fig. 3b).

Regarding Claim 3, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are integrally formed (fig. 3b).

Regarding Claim 4, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are made of wire (par. 32, proximate lines 1-2).

Regarding Claim 5, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions when the device is deployed forms generally an S-shape (fig. 3a).

Regarding Claim 6, Peavey teaches the method of claim 1, wherein each clip-shaped portion is formed from two adjacent loops connected by a connecting portion (26 is formed by loops 34 and 32, Fig. 2a; 38 is formed by loops 48 and 34 and 36 is formed by 46 and 32; 40 is formed by loops 46 and 48; these are connected with the connecting portion, which is the wire between the loops in Fig. 2a)

Regarding Claim 7, Peavey teaches the method of claim 1, wherein deploying the closure device comprises releasing the closure device from a detachment element (27) provided on the device.

Regarding Claim 10, Peavey teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum, comprising: providing a closure device having a proximal end (26) and a distal end (40) and having a generally elongate configuration (par. 42, lines 2-3) and a clip configuration (fig. 3a), wherein when the device is in its elongate configuration the proximal and distal ends are pulled away from each other and when the closure device is in its clip configuration the device has generally an S-shape (fig. 3a), the closure device being releasably attached relative to a delivery device (para. 55); delivering the closure device to the patent foramen ovale with the delivery device, the closure device being held relative to the delivery device in its elongate configuration; and deploying the closure device in the patent foramen ovale, wherein the closure device when deployed includes a first clip-shaped portion positioned around the septum secundum and a second clip-shaped portion positioned around the septum primum (par. 42, figs. 3b and 11); and locking the closure device in its clip configuration after deployment (fig. 3b, the device is locked because of the

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friction provided between the septums and the device, according to the applicants specifications, paragraph 112, the lock can be a friction fit).

Regarding Claim 12, Peavey teaches the method of claim 10, wherein the closure device is held in its elongate configuration distal to a deployment catheter (for a small amount of time a portion of the closure device is in an elongate configuration, para. 55).

Regarding Claim 13, Peavey teaches the method of claim 10, wherein the closure device is delivered by positioning the catheter between the septum primum and septum secundum (par. 42).

Regarding Claim 15, Peavey teaches the method of claim 10, wherein the closure device self-expands to its deployment configuration (par. 33).

Regarding Claim 48, Peavey teaches the method of claim 1, wherein the intermediate segment comprises at least two side-by-side wire portions (38 includes portions of 48 and 34, and 36 includes portions of 46 and 32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peavey in view of Shaw et al. (US 6171329).

Regarding claim 11, Peavey teaches all limitations of preceding dependent claim 10 as previously described, and further teaches wherein the device includes a detachment element (27), but fails to teach wherein the device is delivered using a core wire which releasably engages the detachment element. Shaw teaches a closure device wherein the device includes a detachment element (44) at its proximal end, and the device is delivered using a core wire (42) that releasably engages the detachment element (Fig. 5D).

It would have been obvious to one of ordinary skill in the art to combine Shaw with Peavey, in order to provide exact positioning or repositioning of the device before deployment.

Regarding claim 16, Peavey teaches all limitations of preceding dependent claim 10 as previously described, and further teaches wherein the device includes a detachment element (27), but fails to teach the device includes a plurality of eyelets,

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and the closure device is releasably attached to the delivery device by engaging a core through at least some of the eyelets. Shaw teaches a device includes a plurality of eyelets (44,46,48), and the closure device is releasably attached to the delivery device by engaging a core through at least some of the eyelets (Fig. 5D).

It would have been obvious to one of ordinary skill in the art to use the eyelets of Shaw with the device of Peavey, because the eyelets help to deliver the device and complete the closure of the wall defect (Shaw, col. 9, ll. 4-8).

Response to Arguments

Applicant's arguments with respect to claims 1-7,10-13,15,16, and 48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR


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SUPERVISORY PATENT EXAMINER